

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rudnick et al.

Examiner: D. Isabella

Serial No.: 09/271,304

Group Art Unit: 3738

Filed: March 17, 1999

Docket: 498-67 CON 2

For: NESTED STENT

Dated: May 16, 2000

Date _____ Label No. _____
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deposited this paper or fee with the U.S. Postal Service
and that it was addressed for delivery to the Assistant
Commissioner of Patents, Washington, D.C. 20231 by
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Name (Print)

(Signature)

Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION OF PRIOR INVENTION IN
THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. § 1.131

Sir:

1. We, James J. Rudnick, and Dominik M. Wiktor, both citizens of the United States, residing respectively at 11 Clearwater Court, Mahwah, NJ 07430 and 6441 3rd Palm Point, Saint Petersburg, Florida 33706-2123, are joint inventors of the above-identified application.
2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

for Meadox Medicals, Inc. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to April 1, 1994, i.e. the effective date of U.S. Patent No. 5,876,432, Lau et al. (hereinafter the '432 patent), which was cited by the Examiner in an Office Action mailed December 29, 1999.

3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention was completed in the United States before April 1, 1994 which is a date earlier than the U.S. filing date of the '432 patent. Completion of the invention prior to April 1, 1994, is shown by conception and actual reduction to practice of the invention as evidenced by construction and testing of a nested stent.
4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to April 1, 1994, the following documents being submitted as evidence:
 - a. A Meadox Medicals, Inc. invention disclosure (Exhibit A) bearing dates signed by the inventors and dates signed by witnesses prior to April 1, 1994, the filing date of the '432 patent. (The dates have been redacted to prevent their unnecessary disclosure.) That invention disclosure describes the nested stent of the present invention where the benefits of the device are described as follows: "all of the above being accomplished by providing maximum monofilament wire density in a minimum volume of space by proper nesting of convolutions of formed wire over a mandrel." In an attachment to that invention disclosure, a drawing of the nested

stent is shown. The drawing shown in the attachment to the invention disclosure is substantially similar to the drawings shown in Figures 2 and 8 of the present application. This invention disclosure evidences conception of the invention prior to April 1, 1994.

- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into Table 1.

- 5. The materials submitted herewith establish that the invention was completed, i.e. conceived and reduced to practice at a date prior to April 1, 1994, the filing date of the '432 patent.

6. This declaration is submitted in a response to a first Office Action issued by the Examiner and is therefore believed to be timely filed.
7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: MAY 17, 2009


James J. Rudnick

DATED: _____

Dominik Wiktor

1. GIVE TITLE OF YOUR IDEA:

HI-STRENGTH HI-WIRE DENSITY INTRAVASCULAR EXPANDABLE STENT

2. DESCRIBE YOUR IDEA IN DETAIL AND INCLUDE SKETCH AND FORMULA IF NECESSARY:

Intraluminal Stent characterized by its ability to resist external compressive forces, also to discourage encroachment of cell ingrowth between wires after deployment, yet maintain full flexibility; all of the above being accomplished by providing maximum monofilament wire density in a minimum volume and space. by proper nesting of convolutions of formed wire over a mandrel

3. STATE ADVANTAGES OVER EXISTING PRODUCTS OR METHODS:

Presently used and known Stents, specifically as shown in US Pat 4,886,062 by Wiktor, although similar in design and basic construction do not provide high strength nor tight wire nesting as the Stent of this Invention.

4. ATTACH AND IDENTIFY COPIES OF ALL KNOWN REFERENCES, DRAWINGS, SKETCHES, DESCRIPTIONS, DATA, ARTICLES, TEXTBOOKS, ETC. (Note: All entries made in Laboratory Notebooks, memoranda, correspondence or similar documentation by author, recipient, date, project number, book number, and page number, if applicable. Concept Meeting,

First memo to J. Rudnick, subsequent meeting at MEADOX Dominik M. Wiktor developed thus reduced a theoretical idea to a a working model; several models constructed and expanded over a balloon, additional samples constructed and together with a memo sent to MEADOX

5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:

Dominik M. Wiktor
James J. Rudnick

Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
<i>Dominik M. Wiktor</i>		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 07016
<i>James J. Rudnick</i>		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

WITNESSED AND UNDERSTOOD BY:

Anthony M. Spadaro Signature Anthony M. Spadaro Print Name Date: _____

APPROVED FOR FURTHER PATENT REVIEW:

☐ Yes ☐ No _____ Date: _____

☐ Yes ☐ No _____ Vice President Date: _____

EXECUTIVE COMMITTEE REVIEW:

☐ Approved for Patentability Opinion _____ President Date: _____

☒ Approved for Patent Application *[Signature]* President Date: _____

☐ Other (explain below) _____ President Date: _____

Comments: _____

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PAGE NO.: 1 of 1

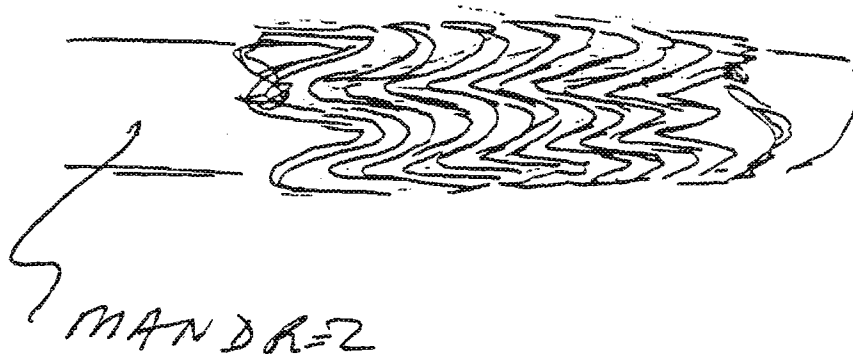
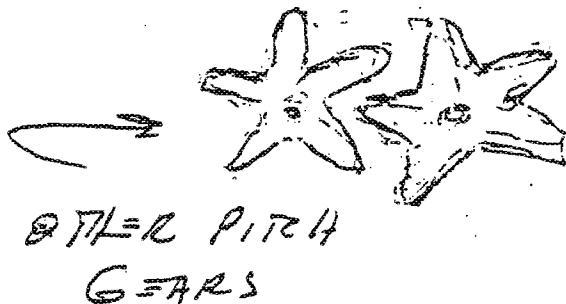
PROJECT NO.:

DATE:

SUBJECT:

H1 STRENGTH - H1 WIRE DENSITY
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PRE-FORMED OVER GEARS



WIRE FORMED
WITH GEARS
FIG 1

James J. Rudnick
JAMES J. RUDNICK

by
RECORDED

Dominik M. Viktor

INVENTOR

DATE

DOMINIK M. VIKTOR

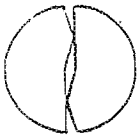
WITNESS

DATE

Anthony M. Friedman

EACH PAGE MUST BE SIGNED, WITNESSED, AND DATED.





Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street
Suite 200
Cambridge, MA 02141
617 661 3552
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Stent Analysis Summary

FINAL ISSUE

For:
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112 Bauer Drive
Oakland, NJ 07436
1-800-221-1542

By:
Product Genesis, Inc.
300 Bent Street, Suite 200
Cambridge, MA 02141
617-661-3552

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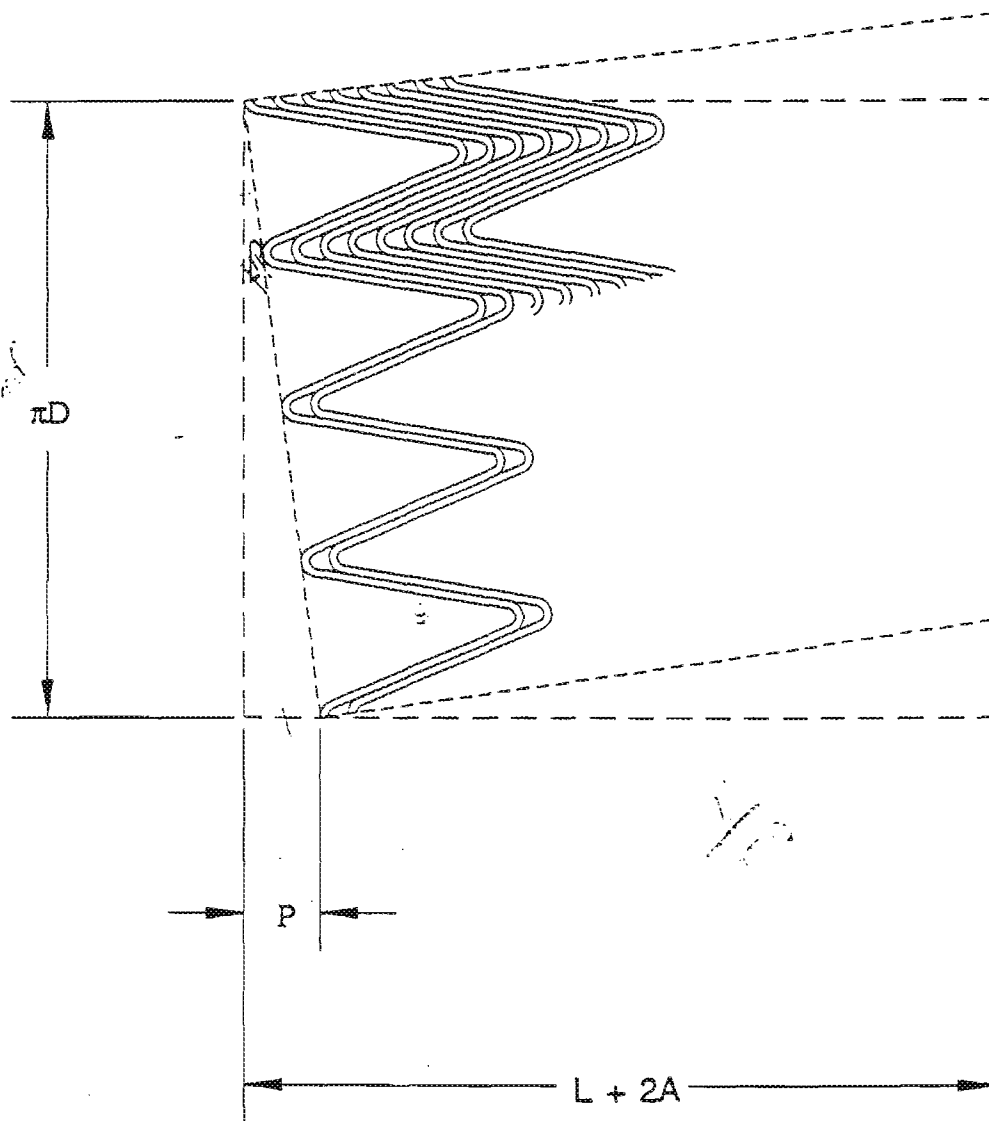
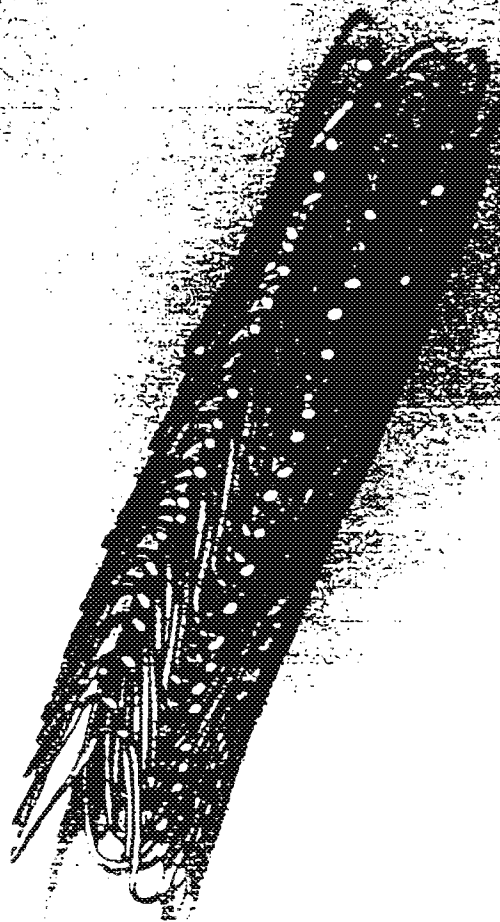
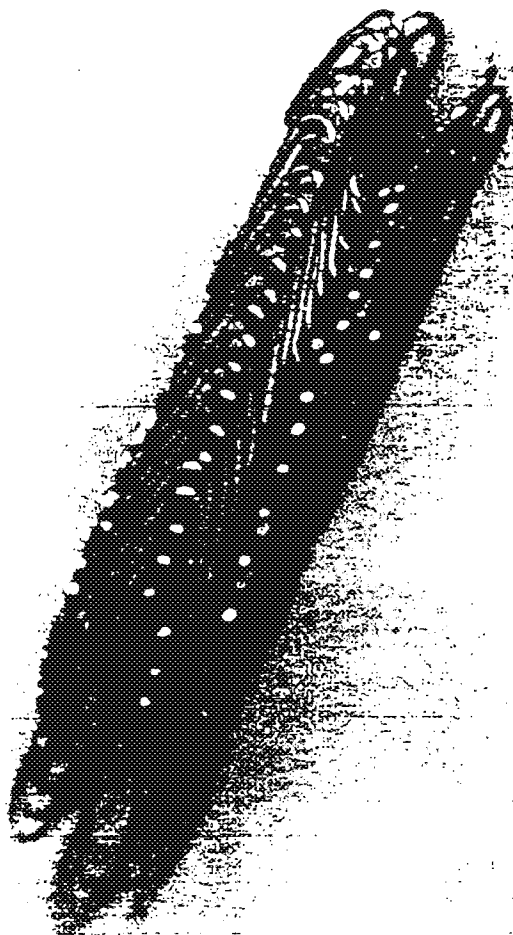


Figure 2-2: Stacked Packing Geometry



1000
900
800
700
600
500
400
300
200
100
0

Figure 1-5

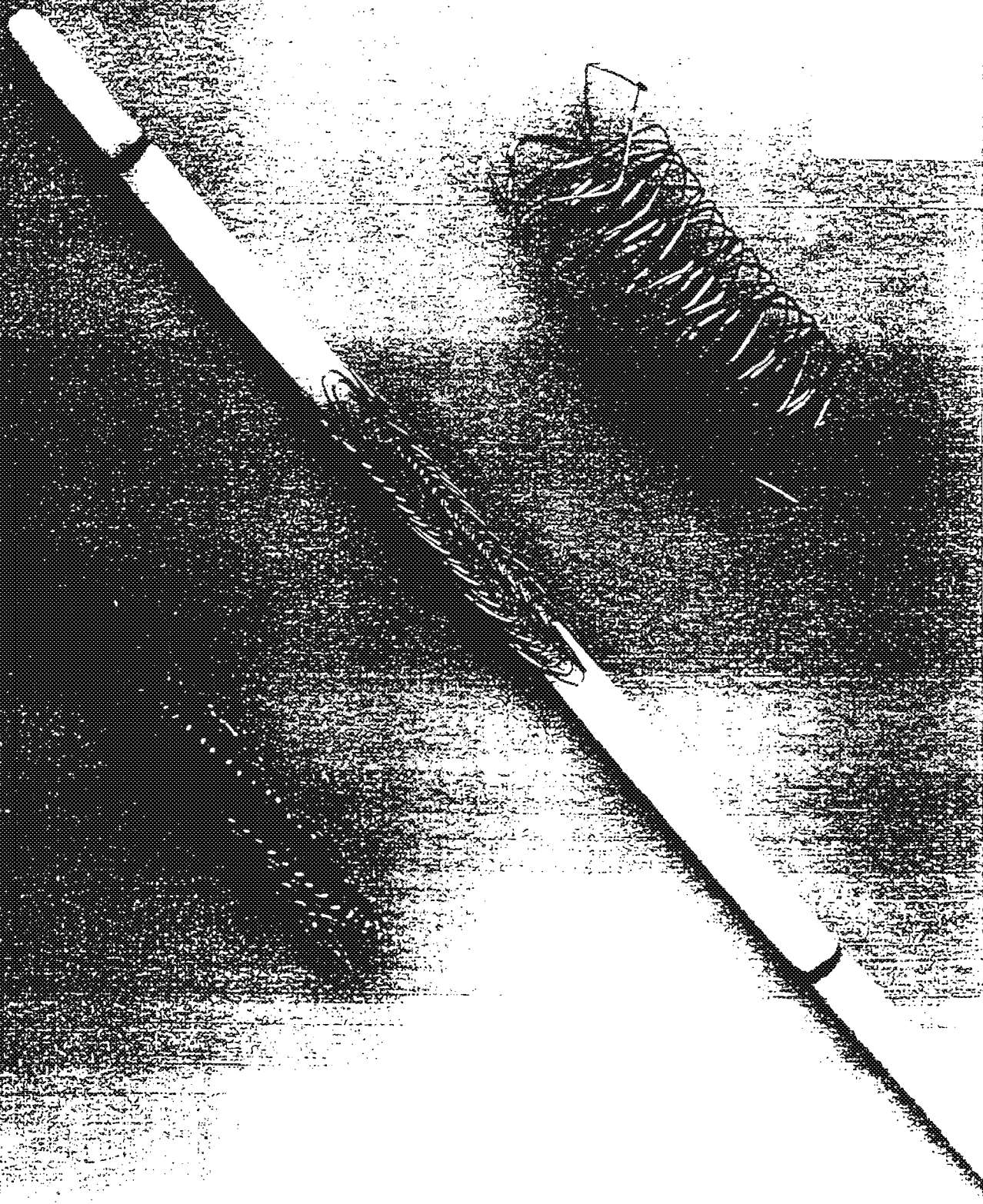






Figure 1-7

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Measos		Stack Packed Slant Geometry		Design Variables:		% Most Optimal Values:		a (")		b (")		M		N		% lost		a	
1	L (")							0.020		0.020		11.3		3		26.0		2582	
2	D (") closed							0.020		0.020		13.3		2		14.7		2915	
3	D (") open							0.010		0.020		17.5		4		44.5		7884	
4	A (psi)							0.010		0.020		22.5		3		28.9		11584	
5	d (")							0.010		0.020		28.5		2		17.2		8507	
6	r (") closed							0.010		0.020									
7	N																		
8	M																		
9																			
10	Lw (")																		
11	Wle Area																		
12	% lost																		
13	T (lb)																		
14	Po																		
15	h																		
16	ko																		
17	Point A																		
18	Vx (lb)																		
19	Vy (lb)																		
20	Mx (lb)																		
21	My (lb)																		
22	Mz (lb)																		
23	a (psi)																		
24	b (psi)																		
25	c (psi)																		
26	Point B																		
27	Vx (lb)																		
28	Vy (lb)																		
29	Mx (lb)																		
30	My (lb)																		
31	Mz (lb)																		
32	a (psi)																		
33	b (psi)																		
34	c (psi)																		

Stress Concentration Variables

R/c	47.244
r/c	0.003

Trigonometric Variables

cos(theta cl)	0.974
sin(theta cl)	0.225
cos(theta op)	0.087
sin(theta op)	0.998

Load Areas and Centroids

Area1	0.00080787
Area2	2.1814E-05
Area3	0.00090787

Equation #:

x1	0.00421641
x2	0.010
x3	0.00421641

Equation #:

13	
15	
13	

Trace

67.000	
--------	--

Meadow		CONFIDENTIAL									
Band Packed Stent Geometry											
Design Variables:											
	L (")	1.000									
	D (") closed	0.157									
	D (") open	0.472									
	Pu (psi)	10.0									
	d (")	0.010									
	N	12									
	M	14.20									
	θ (°) closed	-25.8									
Outputs:											
(Eq #)											
1	λ (") closed	0.041									
4	A (") closed	0.030									
1	λ (") open	0.124									
3	λ (")	0.009									
5	λ (") closed	0.011									
8	θ (") open	72.8									
4	A (") open	0.003									
10	Lw (")	27.403									
	Wire Area	0.274									
11	% lost	44.8									
21	T (lb)	0.168									
22	λ (")	4.908E-10									
12	Pe (psi)	54.2									
26	N	1.02									
27	ko	0.98									
Point A											
17	Vy (lb)	0.000									
17	Vz (lb)	0.013									
18	My (lb)	8.91E-05									
18	Mz (lb)	2.77E-04									
22	σ (psi)	2891.									
23	τ (psi)	352.									
28	e (psi)	3120.									
Point B											
18	Vy (lb)	0.168									
18	Vz (lb)	0.013									
20	My (lb)	0.00E+00									
20	Mz (lb)	5.54E-04									
22	σ (psi)	5813.									
23	τ (psi)	2824.									
28	e (psi)	8173.									
Constraints:											
(Eq #)											
>	0.041										
>	0										
<	0.010										
<	80										
>	0										
Stress Concentration Variables											
Equation #:											
24	R/c	47.244									
25	h/c	0.005									
Trigonometric values:											
cos(theta cl)		0.902									
sin(theta cl)		-0.432									
cos(theta op)		0.300									
sin(theta op)		0.954									
Load Area and Centroids											
Equation #:											
13	Area1	8.721E-05									
15	Area2	0.00031483									
13	Area3	8.721E-05									
Equation #:											
14	x1	0.00130687									
18	x2	0.003									
14	x3	0.00130687									

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DATED: _____

James J. Rudnick

DATED: MAY 18 2000



Dominik Wiktor



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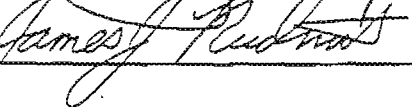
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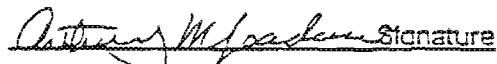
5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:

Dominik M. Wiktor
James J. Rudnick

Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 070
		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

WITNESSED AND UNDERSTOOD BY:



Anthony M. Spadaro Print Name

Date: _____

APPROVED FOR FURTHER PATENT REVIEW:

☐

Yes

☐

No

Date: _____

☐

Yes

☐

No

Vice President

Date: _____

EXECUTIVE COMMITTEE REVIEW:

☐

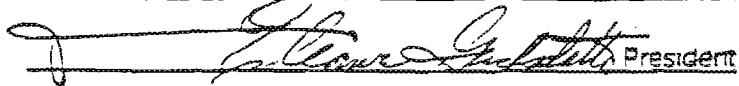
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President

Date: _____

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Approved for Patent Application



President

Date: _____

☐

Other (explain below)

President

Date: _____

Comments: _____

BOOK NO.:

PAGE NO.: 1 of 1

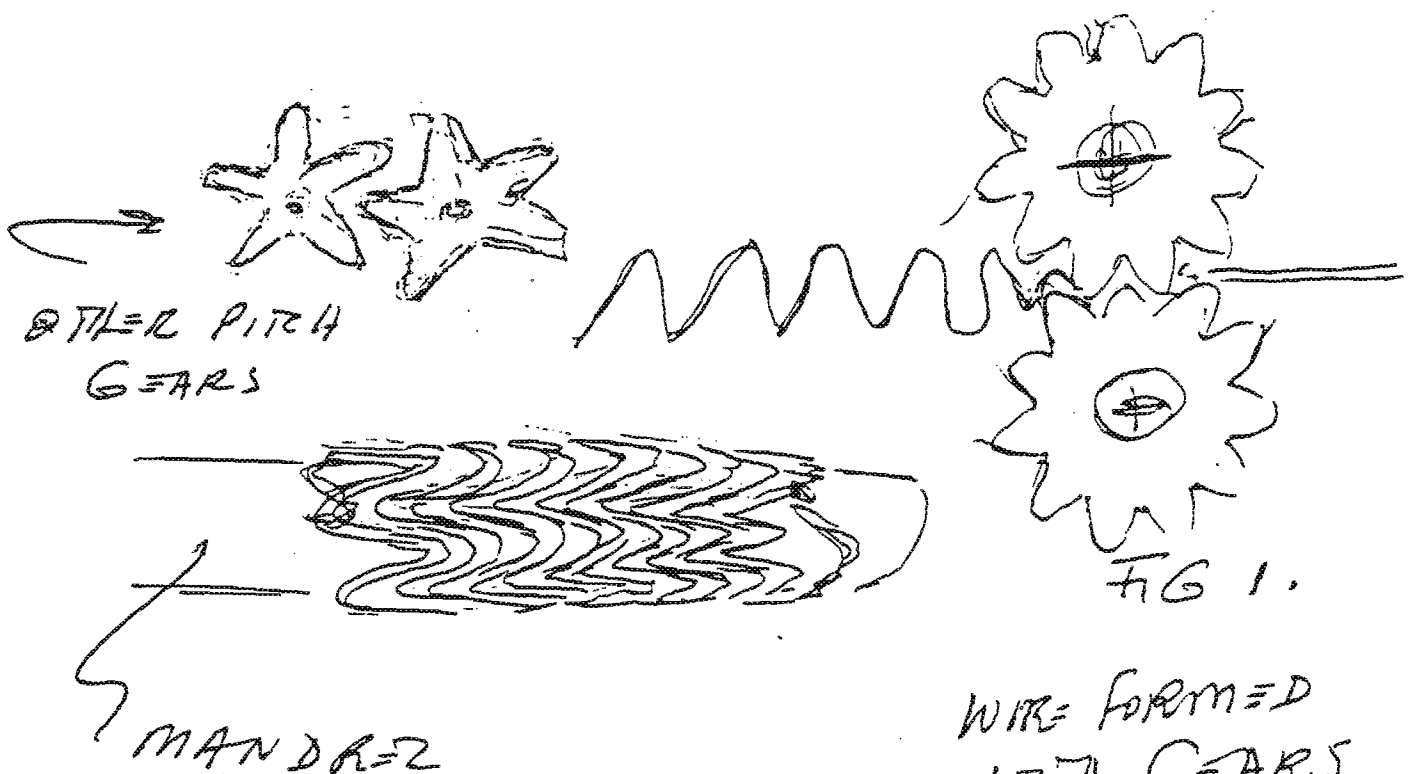
PROJECT NO.:

DATE:

SUBJECT:

H1 STRENGTH - H1 WIRE DENSITY
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PRE-FORMED OVER GEARS



James J. Rudnick
JAMES J. RUDNICK

for
RECORDED

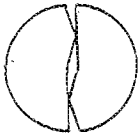
Dominik M. Viktor
INVENTOR
DOMINIK M. VIKTOR

DATE

Anthony M. Spidner
WITNESS

DATE





Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street
Suite 200
Cambridge, MA 02141
617 661 3552
FAX 617 661 0126

Stent Analysis Summary

FINAL ISSUE

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Oakland, NJ 07436
1-800-221-1542

By:
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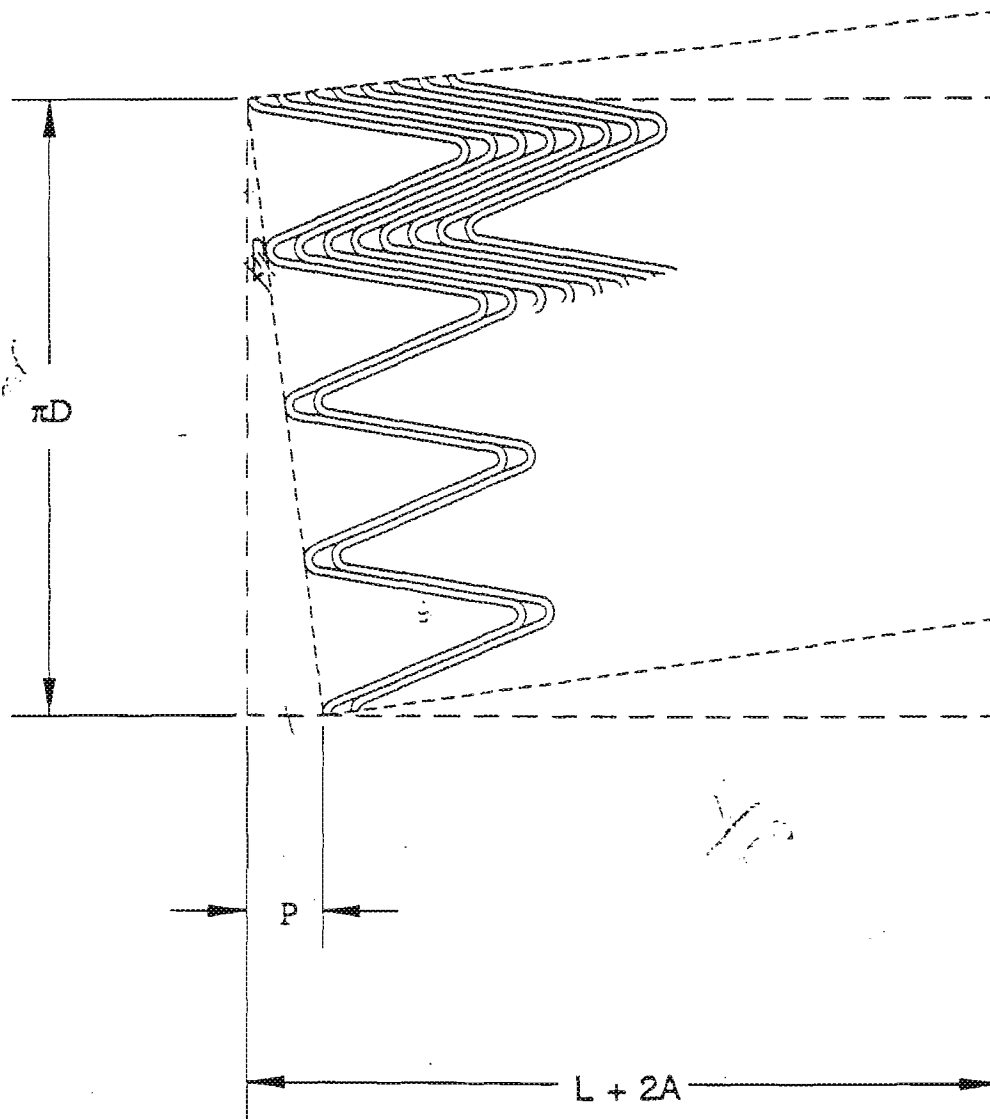
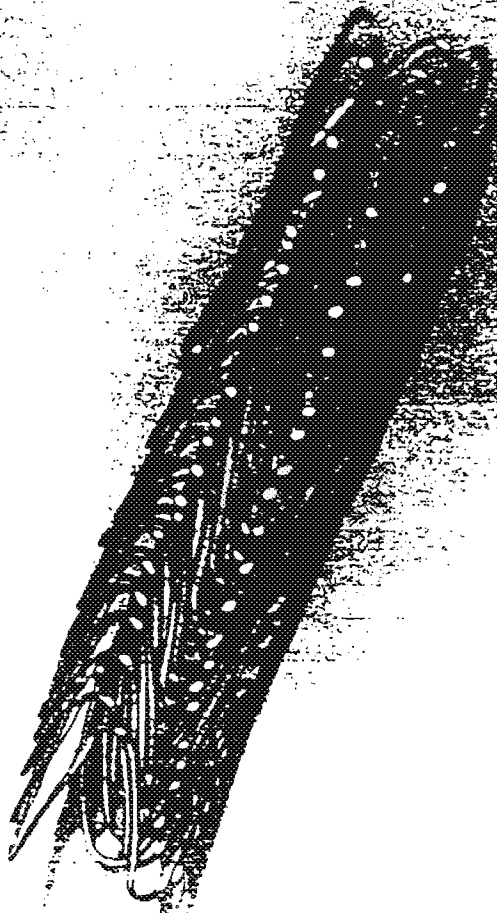
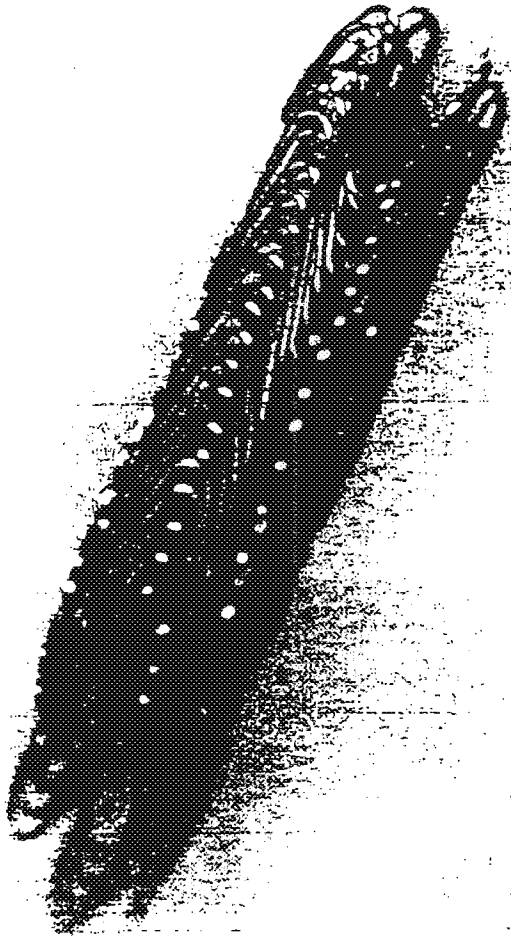


Figure 2-2: Stacked Packing Geometry



11-21001

Figure 1-5

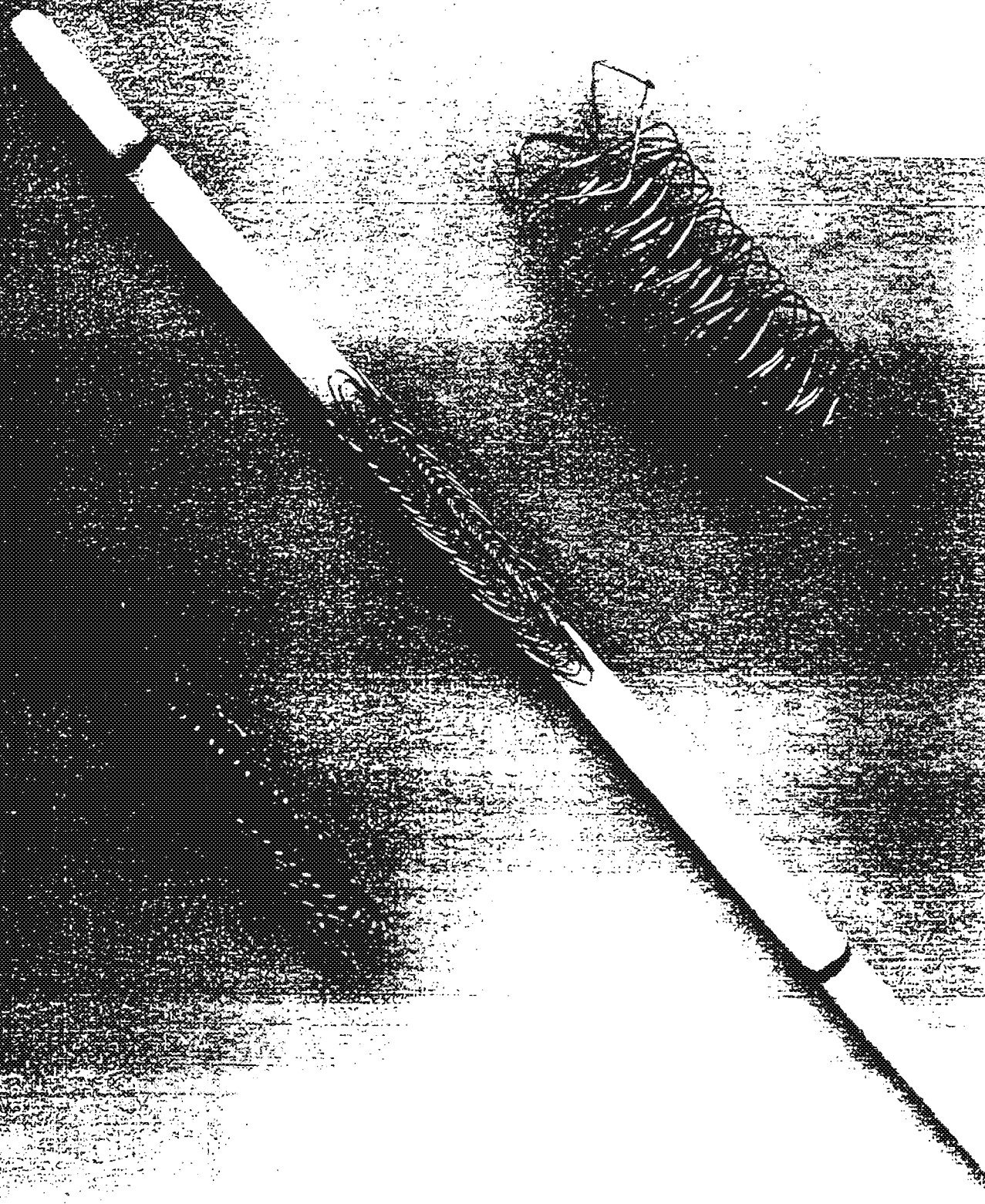


Figure 1.6





Figure 1-2

